식품의약품안전처 **Press Release** 국민 안심이 기준입니다

For IMMEDIATE RELEASE		Date	February 28, 2023 (Tue.)
Division	Medical Device Evaluation Department Cardiovascular and Imaging Devices Division	Director	Roh Hye-Won (043-719-3951)
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<FDS standard to become an international standard>

MFDS supports export of medical devices beyond regulatory barriers with global leadership

- Reappointed as chair of the Work Group 1 : Pre-Market Submission and CSDT of the Global Harmonization Working Party (GHWP) -

□ The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea (Minister Oh Yu-Kyoung) attended the annual meeting of the Global Harmonization Working Party (GHWP*, Riyadh, Saudi Arabia) from February 13 to 16, where it strengthened global network for cooperation in the field of medical devices to take a main role for digital health and sought ways to support the export of domestic products.

* GHWP(Global Harmonization Working Party) : A cooperative organization launched in 1996 to achieve international harmonization of medical device regulations. Currently, it has 33 member countries, including the United States, Japan, China, and Singapore, Technical Committee, and 9 Working Groups. Korea served as the chair country for 2015-2017.

○ At this annual meeting, the MFDS was recognized for its excellent approval/review regulatory capabilities, and was

reappointed as the chair of 'the Work Group 1 [WG1] - Pre-Market Submission and CSDT' (3-year term).

- In addition, with the experience and expertise of having the MFDS' AI medical device guidelines adopted as international common guidelines during its chairmanship of IMDRF*, the MFDS began discussions at the GHWP on adoption of its 'Guidelines on review and approval of AI-based histopathologic in-vitro diagnostic medical devices (software)' as international common guidelines.

  * International Medical Device Regulatory Forum (IMDRF) : A consultative body of medical device regulators from 11 countries, including the US and Europe. It was established to accelerate international regulatory harmonization and convergence for the pre/post-market cycles of medical devices. Korea served as the chair country in 2021.

○ At this meeting, the MFDS' 'Guideline on Review and Approval of AI-based Medical Devices' was added as a significant reference guideline to the guidelines* applied when GHWP member states make a change to categorization of registered medical devices.

  * Categorization of Changes to a Registered Medical Device

□ For reference, 'expanding the application of digital health devices' was selected and discussed as a special topic at this GHWP annual meeting. The representatives of the MFDS, the industry, and hospitals from Korea attended as speakers and presented advanced domestic regulatory system and cases of using innovative products.

○ In particular, the country's first approved digital treatment device* supported by customized regulation like developing preemptive guidelines, smart hospitals with digital technology, and cases of using various AI-based medical devices have attracted much attention.

* Cognitive-Behavioral Therapy for Insomnia (CBT-I) (approved on February 15, 2023 as a digital therapeutic device)

Attachment

Contact Persons

◇ If you have any questions about the content, please contact the persons below.

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